

REMARKS

Claims 1-41 currently appear in this application. The Office Action of July 5, 2005, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Rejections under 35 U.S.C. 112

Claims 13-20, 23-26, 30, 33-35, 38 and 59-62[?] are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

This rejection is respectfully traversed. The term "prevention" was deleted from claims 13-20 and 23-26 by the amendment filed April 1, 2005.

The present specification makes reference to WO/9849188, now U.S. Patent No. 6,410,693, which describes the use of a JNK-interacting protein. Thus, at the time of filing the application that issued as the '693 patent, one skilled in the art knew how to use a JNK-interacting protein to inhibit the JNK kinase pathway. The present invention provides new compounds for this inhibition.

If a statement of utility in the specification contains within it a connotation of how to use, and/or the art

recognizes standard modes of administration are known and contemplated, 35 U.S.C. 112 is satisfied, *In re Johnson*, 282 F.2d 370, 373 127 USPQ 216, 219 (CCPA 1960); *In re Hitchings* 342 F.2d. 80, 87, 144 USPQ 637, 643 (CCPA 1965). For example, it is not necessary to specify the dosage or method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation. If one skilled in the art, based on knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy 35 U.S.C. 112, first paragraph.

The present specification, at page 2, line 24 through page 4, line 30, provides a detailed explanation of the actions of the JNK's and how they influence the progress of neuronal or autoimmune system related disorders. Since methods for interfering with the JNK pathway are known, see below, one skilled in the art can readily discern an appropriate dosage of the compounds of the present invention.

Davis et al., in U.S. Patent No. 6,410,693, based upon an application filed April 28, 1997, long prior to the filing of the present application, describes the JNK signal transduction pathway, and notes that polypeptides have been discovered that interfere with the JNK pathway. For example, [compositions] can be used to treat neurodegenerative diseases

characterized by apoptosis, including Parkinson's disease and Alzheimer's disease, and blood clots. Other conditions that can be treated using the composition and methods of the invention by interfering with the JNK pathway are autoimmune diseases such as arthritis; other conditions characterized by inflammation; and malignancies, such as leukemia... Other conditions that can be treated with [the invention's] compositions include oxidative damage to organs, such as the liver and kidney, and heart diseases, particularly damage due to ischemia/reperfusion and cardiomyopathy. [column 2, lines 17-29] Thus, it is clear that one skilled in the art knew that inhibiting the JNK kinase pathway was useful in treating a variety of diseases claimed in the present application. Dosages and administration methods are disclosed at column 22, lines 1-47 and column 30, lines 39-67.

Claims 10, 13-20, 23-26, 32-34 and 37-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is respectfully traversed. With respect to the Examiner's assertion that it is not known which diseases are capable of being responsive to the activity of JNK, it is respectfully submitted that it is not necessary to know all diseases that would respond to the modulation of JNK.

The present inventors have invented compounds that modulate the activity of the JNK pathway. Therefore, any disease that is affected by this modulation would necessarily be treated by such modulation. By identifying compounds that modulate the activity of the JNK pathway, applicants are not pre-empting the efforts of others, because applicants identified compounds that modulate the activity of the JNK pathway. Merely identifying additional diseases that are affected by this modulation does not alter the fact that the present inventors discovered compounds that alter this pathway, and this can treat any disease affected by this modulation.

Claims 1-3, 5-26, 32-34, and 37-41 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is respectfully traversed. Claims 1-3, 5, 8, 10 and 13 have been amended to overcome the indefiniteness requirement. With respect to claim 8, the Examiner alleges that there is no basis in the specification for the thioxo moiety.

Attention is directed to the specification at page 11, lines 18-21, for reference to thioxo-dihydropyridine and its tautomer. Claim 5 has been amended to include this moiety.

Claims 1-3, 5-10 and 13-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The omission of an element from the proviso is said to constitute new matter when the specification specifically excludes the compounds.

This rejection is respectfully traversed. The proviso cancelled by the previous amendment has been re-entered.

Claims 2, 3 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner states that the definition of Y as a piperidino group is said not to be described in the specification for the genus of formula 1.

This rejection is respectfully traversed. The specification as filed at page 11, lines 5-16, specifically states that in a preferred embodiment of the invention, Y is a piperidine or piperazine moiety.

As the Examiner is well aware, "piperidine" is the name of the ring, and "piperidino" is the name of the group. They both mean the same moiety, namely, a 6-membered heterocyclic ring containing one nitrogen atom. Submitted herewith is a printout from Vasudha Pharma Chem. Ltd. showing 4-piperidino piperidine, which compound is two piperidine rings joined together.

Claims 1-3, 5-10 and 13-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is respectfully traversed.

With respect to claim 1, claim 1 has been amended to replace the "()" with "[]". The semicolon on line 5 of page 5 of the amendment has now been deleted.

Claim 3 has been amended to recite "a sulfonamide compound or a composition according to claim 1."

Claim 9 has been amended to recite that "n" is an integer of from 0 to 4. Claim 8, from which claim 9 depends, recites n as being 1. "Compounds" has been deleted from claim 9. Claim 9 has been amended to recite "nitro, cyano" in place of -nitro cyans-. Support for this amendment can be found in the specification at page 9, lines 22-25. Claim 9 has also been amended to make the "W" in the last paragraph on page 10 and the "S" in the penultimate paragraph of page 11 of the amendment lower case letters. The phrase "substituted or unsubstituted C₂-C₄ alkyl optionally containing 1-3 heteroatoms and optionally fused with aryl or heteroaryl" has been deleted from the definition of L¹ and L². "-SO₂NR³'" has been replaced by "-SO₂NR³R³'". "pr" has been deleted from claim 9.

Claim 10 has been amended to recite "compound" rather than -compounds- and that R¹ is H.

Claim 10 depends from claim 9, which depends from claim 8. Claim 8 depends from "any of the preceding claims." Claim 4 recites that L^1 can be a substituted or unsubstituted cyclic C_4 - C_8 -alkyl optionally containing 1-3 heteroatoms, and that R^3 can be H. It is respectfully submitted that these recitations in claim 4 provide sufficient antecedent basis for this recitation of L^1 .

Claim 9, from which claim 10 depends, recites that R^3 can be aryl- C_1 - C_4 -alkyl. Claim 10 has been amended to recite that the aryl group is C_1 - C_4 rather than C_1 - C_6 .

It is not understood why claims 27-31 are considered to be indefinite because of the recitation of "compounds." Claim 1 recites "compounds", and claims 27-28 recite compounds in which n can be one of several integers. Claims 29 and 31 have been amended to recite "compositions." Claim 30, in which n is limited to 1, has been amended to recite "The composition."

Claim 36 has been amended to replace " L^1 " with $-L^1--$, for which there is antecedent basis in claim 10.

Claim Objections

Claim 22 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim is not stated in the alternative.

Claim 22 has now been amended to delete "where Ar² and R¹ are as defined as in claim 1", because claim 22 depends from claim 1 and therefore these definitions are included in the limitations in claim 22.

Provisional Obviousness-type Double Patenting

Claims 1-3 and 5-26 are provisionally rejected under the doctrine of obviousness-type double patenting over copending application 10/381,197.

This rejection is respectfully traversed. Serial No. 10/381,197 is subject to a restriction requirement mailed August 31, 2005. There is no indication of what claims will be elected. Therefore, it is respectfully submitted that this provisional double patenting rejection is premature.

Claims 1-3 and 5-26 are rejected under the doctrine of obviousness-type double patenting over copending application 10/381,200.

This rejection is respectfully traversed. The amendment filed July 5, 2005, deleted the definition of Ar² as aryl or heteroaryl, and limits Ar² to a thienyl group carrying at least one hydrophilic substituent. Therefore, there is no longer a problem with obviousness-type double patenting.

Claims 1-3 and 5-41 are provisionally rejected under the doctrine of obviousness-type double patenting over copending application 10/381,665.

This rejection is respectfully traversed.

Application 10/381,665 has not yet been examined. There is no way of knowing what claims in 10/381,665 will eventually be allowed. It is thus respectfully submitted that a provisional obviousness-type double patenting rejection is premature.


Election/Restriction

Claim 4 has been withdrawn from consideration.
Claims 3 and 13 have been amended to delete the nonelected compounds.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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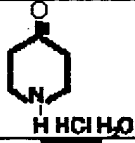
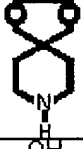



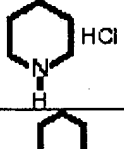

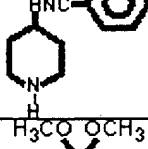
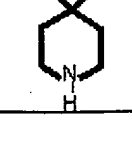
Vasudha Pharma Chem Ltd.

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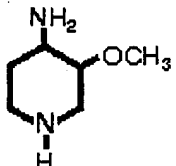
Pharma Intermediates API's Under Development

PHARMA INTERMEDIATES

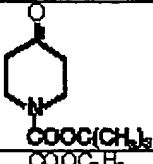
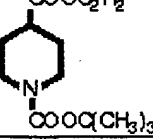
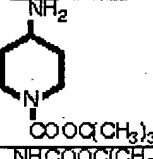
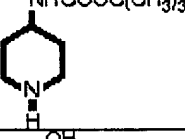
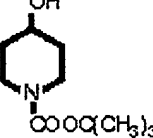
SPECIALISED PIPERIDONE DERIVATIVES

S.No.	NAME OF THE PRODUCT	FORMULA	C.A.S. No.
3.1	4-Piperidone (Mono Hydro Hydrochloride)		40064-34-4
3.2	4-Piperidone-Ethylene Ketal		177-11-7
3.3	4-Hydroxy Piperidine		5382-16-1
3.4	4-Amino Piperidine		13035-19-3
3.5	4-Phenyl Piperidine		771-99-3
3.6	4-Chloro Piperidine HCl		
3.7	4-Piperidino Piperidine		4879-50-1
3.8	4-Benzimido Piperidine		33953-37-6
3.9	4,4 Di Methoxy Piperidine		

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3.10	4-Amino-3-Methoxy Piperidine		
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TERT BOC PIPERIDONE DERIVATIVES

4.1	N-tert Boc-4-Piperidone		79099-07-3
4.2	N-Boc-4-Carboxy Piperidine		142851-03-4
4.3	N-Boc-4-Amino Piperidine		
4.4	4-Tert-Boc-Amino Piperidine		73874-95-0
4.5	N-Boc-4-Hydroxy Piperidine		

Next